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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,066	05/16/2002	Enrique Matinez-Force	ARNO118344	4299

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,066

Applicant(s)

MATINEZ-FORCE ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 16 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/326,501 and 60/180,455.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/16/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed May 16, 2002 has been entered.

Claims 3-5, 7-9, 11-14 and 16-18 are newly amended.

Claims 1-18 are pending.

Election/Restrictions

1. Claims 10, 11 and 18 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 30, 2004.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration fails to claim priority as a continuation-in-part to U.S. application 09/326,501, which claims benefit of provisional application 60/180,455.

Priority

A statement reading "This is a 371 of PCT/EP00/05150, filed June 5, 2000" should be added to the continuity data in the first sentence of the specification in order to provide a complete recitation of the priority claimed. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 14 and 16, and all claims dependent thereon are indefinite in the recitation of “an oil” in the first line, as it is unclear what this means. Is it referring to a fraction of the oil in the seed? Amendment of the claim to recite “the oil” would overcome the rejection.
6. Claims 1-3, and all claims dependent thereon are indefinite in the recitation of the abbreviation “TAG”, since this could refer to any number of things. Amendment of the claims to recite “triacylglycerol”, in the first instance, is suggested.
7. Claim 13 is indefinite in the recitation of “Plants producing plant seeds”, as it is unclear if the plants must be producing seeds to be covered by the claim. Amendment of the claims to read “Plants that produce the plant seeds of claim 1”.
8. Claims 12 and 13 are indefinite in the recitation of “according to claim 1” since it is unclear if this is open or closed language. It is also unclear if this refers to the seeds of claim 1, which have all of the recited characteristics, or if it may encompass seeds having only some of the recited characteristics. Amendment of the claims to read “plant seeds of claim 1” would overcome the rejection.
9. Claim 15 is indefinite in the recitation of “desired levels”, since it is unclear what the desired levels are in parts h) and j).

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to plants grown from the seeds according to claim 1. However, there is no description of the phenotypic or genotypic characteristics of the claimed plants, and the particular oil characteristics of the seed does not describe the characteristics that will be present in the plant grown from the seed.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

In the present case, the method of obtaining the claimed plants from the seed is known. However, no description of the claimed plants that defines the genus has been set forth.

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Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

12. Claims 1-9 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a sunflower seed that contains oil having more than 40 wt% of oleic acid and more than 12 wt% stearic acid and a maximum of 10 wt% of saturated fatty acid groups in the sn-2 position that are produced by crossing a sunflower plant grown from seeds of the HOHT line that are deposited at ATCC as PTA-628 with a sunflower plant grown from seeds of CAS-3, does not reasonably provide enablement for a seed of any plant species having the claimed characteristics and produced by any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only discloses a sunflower seed that contains oil having more than 40 wt% of oleic acid and more than 12 wt% stearic acid and a maximum of 10 wt% of saturated fatty acid groups in the sn-2 position that are produced by crossing a sunflower plant grown from seeds of the HOHT line that are deposited at ATCC as PTA-628 with a sunflower plant grown from seeds of CAS-3. The specification does not disclose any other seeds from any other plant species or produced by any other method that will produce a seed having the claimed properties.

Yet, obtaining a plant seed having high levels of oleic acid and high levels of stearic acid is highly unpredictable. Different plant species have different profiles of fatty acid

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composition depending on the presence and expression of the different enzymes that are involved in fatty acid biosynthesis, as well as mechanisms for regulating the expression and function of these enzymes. Battey et al teach that there are tens of thousands of plant species having nearly a thousand different fatty acids (page 122), and that the biochemical synthesis of TAG is complex and “the final composition of TAG is determined by many interdependent factors”, stating that “the machinery for synthesis and transport of desired fatty acids species must be in place. The supply of fatty acids for TAG must meet the demand”, and “enzymes at each stage of TAG synthesis must be able to use the intermediates containing the species at a competitive rate (page 123). Therefore, it is highly unpredictable which plant species would be able to produce a seed having the claimed characteristics, and the specification provides no guidance with regard to plants or methods that could be used to produce said plant from any other plant species.

Furthermore, Martinez-Force et al (J. Agric. Food Chem. 46: 3577-3582, 1998 in IDS) teaches that the particular fatty acid composition of a seed changes as the seed develops and also changes depending on the growth temperature (page 3579). Martinez-Force et al also teach that varying growth temperature can have a different affect on different plant species (page 3580, the paragraph bridging the columns). Therefore, it is unclear what temperature a given species would be grown under and at what stage of development a seed of any given species would be analyzed.

Given the high level of unpredictability of producing a plant seed having the claimed high levels of oleic acid and high levels of stearic acid, as evidenced above; given the lack of working examples of seeds from other plant species having the claimed characteristics; given

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the absence of guidance with regard to the production and analysis of seeds from other plant species; given the breadth of the claims which encompass plant seeds of any of tens of thousands of plant species and methods of producing the same; and given the state of the prior art and the high level of skill in the art of manipulation of oil composition in a plant; it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

13. Claims 1-3, 5-8, 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hawkins et al (The Plant Journal 13(6): 743-752, 1998 in IDS), as supported by Kridl (U.S. Patent 6,365,802).

The claims are drawn to plant seeds having oil having more than 40 wt% of oleic acid and more than 12 wt% stearic acid and a maximum of 10 wt% of saturated fatty acid groups in the sn-2 position. Claims 12 and 13 are drawn to plants having no recited properties.

Hawkins et al teach oil from seed of *Garcinia morella* that has 46.4% stearic acid and 49.5% oleic acid (page 744, Table 1). The reference is silent with regard to saturated fatty acids at the sn-2 position of TAG. However, Kridl teaches that “there is a tendency for such enzymes from many temperate and tropical crop species to allow either a saturated or an unsaturated fatty acid at the sn-1 or the sn-3 position, but only an unsaturated fatty acid at the sn-2 position of TAGs” (column 2, lines 58-62). The USPTO does not have sufficient facts to determine whether the respective seeds are “inherently the same”. The USPTO cannot

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conclude that the subject matter of the claims would have been obvious since it cannot determine whether the seeds differ. With these conditions, where the prior art seed appears to be identical to the claimed seed except that the prior art is silent to the characteristic of saturated fatty acids at the sn-2 position of the TAG that is claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Thus the claimed invention is prima facie obvious, if not anticipated, by Hawkins et al.

14. Claims 1-3, 5-9, 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Osorio et al (Crop Science 35(3): 739-742, 1995 in IDS), as supported by Kridl (U.S. Patent 6,365,802) and Martinez-Force (J. Agric. Food Chem. 46(9):3577-3582 in IDS).

The claims are drawn to plant seeds having oil having more than 40 wt% of oleic acid and more than 12 wt% stearic acid and a maximum of 10 wt% of saturated fatty acid groups in the sn-2 position. Claims 12 and 13 are drawn to plants having no recited properties.

Osorio et al teach oil from seed of sunflowers that has at the upper limit of the range given, 13.5% stearic acid and 44.4% oleic acid of CAS-4 in the data from Table 2, where stearic acid may be 113+22, and oleic acid may be 346+95. In addition, Martinez-Force teaches the variability of fatty acid composition depending on the time of seed development and the growth temperature. Martinez-Force et al teach that CAS-4 can have an oleic acid level of 45.9% (page 3579, the second column). Osorio et al is silent with regard to saturated fatty acids at the sn-2 position of TAG. However, Kridl teaches that "there is a tendency for such

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enzymes from many temperate and tropical crop species to allow either a saturated or an unsaturated fatty acid at the sn-1 or the sn-3 position, but only an unsaturated fatty acid at the sn-2 position of TAGs” (column 2, lines 58-62). The USPTO does not have sufficient facts to determine whether the respective seeds are “inherently the same”. The USPTO cannot conclude that the subject matter of the claims would have been obvious since it cannot determine whether the seeds differ. With these conditions, where the prior art seed appears to be identical to the claimed seed except that the prior art is silent to the characteristic of saturated fatty acids at the sn-2 position of the TAG that is claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Thus the claimed invention is prima facie obvious, if not anticipated, by Osorio et al.

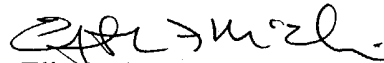
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM